



Proton Beam Therapy Clinical Coverage Criteria

Overview

Proton beam therapy (PBT) is a form of external radiation therapy in which positively charged subatomic particles (protons) are precisely targeted to a specific tissue mass using a sophisticated stereotactic treatment planning and delivery system. The goal of PBT is to deliver a higher target dose with lower normal tissue exposure than is possible with conventional photon irradiation, thereby improving local control of tumors and reducing acute and late complications.

Conventional external beam radiation therapy (EBRT), three-dimensional conformal radiation therapy (3D-CRT), and intensity modulated radiation therapy (IMRT) are delivered via photon beams. Proton beams differ from photon beams mainly in the way they deposit energy in living tissue. Whereas photons deposit energy in small packets all along their path through tissue, protons deposit much of their energy at the end of their path (called the Bragg peak) and deposit less energy along the way. In theory, use of protons should reduce the exposure of normal tissue to radiation, possibly allowing the delivery of higher doses of radiation to a tumor.

PBT is considered reasonable in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient and cannot be adequately achieved with photon-based radiation therapy.

Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care (Commercial/Exchange)

Prior authorization is required for proton beam therapy.

Medicare Advantage

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for proton beam therapy. Medicare does not have an NCD for proton beam therapy. National Government Services, Inc., the Part A and B Medicare Administrative Contractor with jurisdiction in the Plan's service area has an LCD for Proton Beam Therapy (L35075) (Medicare Coverage Database search 08/22/2024).

Coverage criteria for proton beam therapy are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

Link: National Government Services, Inc. [LCD Proton Beam Therapy \(L35075\)](#)

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for proton beam therapy (MassHealth website search 08/22/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to MassHealth ACO and Community Care members.

Effective for dates of service on or after September 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for spinal cord stimulation.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Proton Beam Radiotherapy (PBRT)
- InterQual® CP:Procedures, Proton Beam Radiotherapy (PBRT) (Pediatric)

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Documentation Requirements

Documentation in the patient medical record must:

1. Support one or more indications as described in InterQual® Criteria.
2. Include a treatment prescription that defines the goals of the treatment plan – including specific dose-volume parameters for the target and nearby critical structures – as well as

pertinent details of beam delivery, such as the method of beam modulation, field arrangement, and expected positional and range uncertainties.

3. Include a treatment plan, signed by a physician, which meets the prescribed dose-volume parameters for the clinical target volume and surrounding organs at risk in the presence of expected uncertainties.
4. Describe the target setup verification methodology, including patient positioning, immobilization, image guidance and frequencies.
5. Include verification of planned dose distribution via independent dose calculation or physical measurement.

Exclusions

- While proton beam therapy is not a new technology, there is a need for continued clinical evidence development and comparative effectiveness analyses for the appropriate use of proton beam therapy for the following conditions:
 - Breast cancer
 - Esophageal cancer
 - Gastric cancer
 - Gynecologic cancer
 - Lung cancer
 - Lymphoma (Hodgkin and non-Hodgkin)
 - Pancreatic cancer
 - Prostate cancer

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Selection of the correct proton beam delivery code is based on the complexity and compensation of the treatment:

- Simple proton beam therapy delivery to a single treatment area is billed with either CPT 77522 (with compensation) or CPT 77520 (without compensation).
- Intermediate proton beam therapy delivery to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports with custom blocks and compensators is billed with CPT 77523.
- Complex proton beam therapy delivery to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators is billed with CPT 77525.

Code	Description
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex

References

1. American Society for Radiation Oncology (ASTRO) Model Policy: Proton Beam Therapy.2022. Available at: <https://www.astro.org/daily-practice/reimbursement/model-policies>. Accessed 08/22/2024.
2. ASTRO. Proton Beam Therapy for Prostate Cancer Position Statement. Available at: <https://www.astro.org/daily-practice/reimbursement/model-policies/proton-beam-therapy-for-prostate-cancer-position-statement>. Accessed 08/22/2024.
3. Grutters JP, Pijls-Johannesma M, Ruyscher DD, et al. The Cost-Effectiveness of Particle Therapy in Non-Small Cell Lung Cancer: Exploring Decision Uncertainty and Areas for Future Research. *Cancer Treat Rev*. 2010;36(6):468-76.
4. Grutters JP, Kessels AG, Pijls-Johannesma M, et al. Comparison of the Effectiveness of Radiotherapy with Photons, Protons and Carbon-Ions for Non-Small Cell Lung Cancer: A Meta-Analysis. *Radiother Oncol*. 2010;95(1):32.40.

5. Marucci L, Ancukiewicz M, Lane AM, et al. Uveal Melanoma Recurrence After Fractionated Proton Beam Therapy: Comparison of Survival in Patients Treated with Reirradiation or with Enucleation. *Int J Radiat Oncol Biol Phys*. 2011 Mar 1;79(3):842-6.
6. Marucci L, Lane AM, Egan KM, et al. Conservation Treatment of the Eye: Conformal Proton Reirradiation for Recurrent Uveal Melanoma. *Int J Radiat Oncol Biol Phys*. 2006;64(4):1018-22.
7. MacDonald EC, Cauchi P, Kemp EG. Proton Beam Therapy for the Treatment of Uveal Melanoma in Scotland. *Br J Ophthalmol*. 2011;95(11):1691-5.
8. Foote RL, Stafford SL, Petersen IA, et al. The Clinical Case for Proton Beam Therapy. *Radiat Oncol*. 2012 Oct 22;7:174.
9. National Government Services Inc. Local Coverage Determination (LCD) Proton Beam Therapy (L35075). Original Effective Date 10/1/2015. Revision Effective Date 10/01/2019. Available at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. Accessed 08/22/2024.
10. National Government Services, Inc. LCD Reference Article: Billing and Coding: Proton Beam Therapy (A56827). Original Effective Date 11/07/2019. Revision Effective Date 10/01/2021. Available at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56827&ver=12>. Accessed 08/22/2024.
11. Wisenbaugh ES, Andrews PE, et al. Proton beam therapy for localized prostate cancer 101: basics, controversies, and facts. *Rev Urol*. 2014;16(2):67-75.
12. Doyen J, Bondiau PY, Bénéziéry K, et al. Current situation and perspectives of proton therapy. *Cancer Radiother*. 2015 May;19(3):211-9.
13. Pugh TJ, Lee AK. Proton beam therapy for the treatment of prostate cancer. *Cancer J*. 2014 Nov-Dec;20(6):415-20.
14. Rahmi A, Mammar H, Thariat J, et al. Proton beam therapy for presumed and confirmed iris melanomas: a review of 36 cases. *Graefes Arch Clin Exp Ophthalmol*. 2014 Sep;252(9):1515-21.
15. Schiller KC, Habl G, Combs SE. Protons, photons, and the prostate - is there emerging evidence in the ongoing discussion on particle therapy for the treatment of prostate cancer? *Front Oncol*. 2016;6:8.
16. Mishra MV, Aggarwal S, Bentzen SM, et al. Establishing Evidence-Based Indications for Proton Therapy: An Overview of Current Clinical Trials. *Int J Radiat Oncol Biol Phys*. 2017 Feb 1;97(2):228-235.
17. Tian X, Liu K, Hou Y, Cheng J, Zhang J. The evolution of proton beam therapy: Current and future status. *Mol Clin Oncol*. 2018 Jan;8(1):15-21.
18. American College of Radiology(ACR) and American Radium Society (ARS). ACR–ARS Practice Parameter for the Performance of Proton Beam Radiation Therapy. Revised 2023. Effective January 1, 2024. Available at: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Proton-Therapy-RO.pdf>. Accessed 08/22/2024.
19. ACR and the American Association of Physicists in Medicine (AAPM). ACR–AAPM Technical Standard for Medical Physics Performance of Proton Beam Radiation Therapy. Revised 2023. Effective January 1, 2024. Available at: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Proton-Therapy-TS.pdf>. Accessed 08/22/2024.

Policy history

Origination date:	11/15/2012
Approval(s):	Technology Assessment Committee: 11/15/2012, 12/03/2014 (updated template, references, criteria expanded) 12/15/2015 (updated references), 03/22/2017 (updated references), 03/28/2018 (updated Medicare plan coverage, updated references), 03/27/2019 (updated references), 07/10/2021 (added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 08/27/2024 (annual review, adopted InterQual® Criteria effective 09/01/2024, updated References).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.